Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1-161. (Canceled)

162. (Previously Presented) A fenofibrate composition comprising granulates, wherein the granulates comprise inert carrier particles coated with an admixture comprising at least one hydrophilic polymer and micronized fenofibrate.

163. (Previously Presented) The composition of claim 162, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

164. (Previously Presented) The composition of claim 162, wherein the inert carrier particles have a particle size between 50 and 500 microns.

165. (Previously Presented) The composition of claim 162, wherein the inert carrier particles have a particle size between 100 and 400 microns.

166. (Previously Presented) The composition of claim 162, wherein the inert carrier particles comprise lactose.

167. (Previously Presented) The composition of claim 162, wherein the inert carrier particles are hydrosoluble.

168. (Previously Presented) The composition of claim 162, wherein the at least one hydrophilic polymer is a mixture of at least two hydrophilic polymers.

169. (Previously Presented) The composition of claim 162, wherein one or more of the inert carrier particles are isolated and/or agglomerated together.

170. (Previously Presented) The composition of claim 162, wherein the composition is in the form of a tablet.

171. (Previously Presented) The composition of claim 162, wherein the hydrophilic polymer is polyvinylpyrrolidone.

172. (Previously Presented) The composition of claim 162, wherein the composition further comprises at least one pharmaceutical excipient.

173. (Previously Presented) The composition of claim 172, wherein the at least one pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

174. (Previously Presented) The composition of claim 162, wherein the granulates further comprise at least one outer phase and/or layer.

175. (Previously Presented) The composition of claim 174, wherein the at least one outer phase and/or layer comprises at least one pharmaceutical excipient.

176. (Previously Presented) The composition of claim 175, wherein the at least one pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

177. (Previously Presented) The composition of claim 162, wherein two or more of the granulates are agglomerated together.

178. (Previously Presented) The composition of claim 162, wherein the micronized fenofibrate has a particle size less than or equal to 20 μm.

179. (Previously Presented) The composition of claim 178, wherein the micronized fenofibrate has a particle size less than or equal to 10 μm.

180. (Previously Presented) The composition of claim 162, wherein the inert carrier particles comprise lactose, saccharose, hydrolyzed starch, or a mixture of two or more thereof.

181. (Previously Presented) The composition of claim 162, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture of two or more thereof.

182. (Previously Presented) The composition of claim 162, further comprising at least one surfactant.

183. (Previously Presented) The composition of claim 182, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

184. (Previously Presented) The composition of claim 182, wherein the surfactant is sodium laurylsulfate.

185. (Previously Presented) The composition of claim 182, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture of two or more thereof.

186. (Previously Presented) The composition of claim 162, wherein the inert carrier particles are present in an amount of 10 to 75% by weight, the micronized fenofibrate is present in an amount of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

187. (Previously Presented) The composition of claim 186, wherein the inert carrier particles are present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

188. (Previously Presented) The composition of claim 162, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

189. (Previously Presented) A process for preparing the composition of claim 162, comprising the steps of:

(a) preparing a micronized fenofibrate suspension in a solution comprising at least one hydrophilic polymer, and, optionally, at least one surfactant;

(b) spraying the micronized fenofibrate suspension from step (a) onto inert carrier particles to form granules; and

(c) optionally coating the granules from step (b) with one or more phase(s) or layer(s).

190. (Previously Presented) The method of claim 189, wherein step (b) is carried out in a fluidized-bed granulator.

191. (Previously Presented) The method of claim 189, further comprising compressing the granules of step (b) or step (c).

192. (Currently Amended) A fenofibrate composition comprising ~~consisting essentially of~~ granules, wherein the granules comprise: (i) carrier particles; and (ii) one or more layers comprising an admixture of micronized fenofibrate and at least one hydrophilic polymer, wherein the one or more layers are deposited on the carrier particles.

193. (Previously Presented) The composition of claim 192, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

194. (Previously Presented) The composition of claim 192, wherein the carrier particles comprise lactose, saccharose, hydrolyzed starch, or a mixture of two or more thereof.

195. (Previously Presented) The composition of claim 192, wherein the hydrophilic polymer is polyvinyl pyrrolidone, poly(vinylalcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose; gelatin, or a mixture of two or more thereof.

196. (Previously Presented) The composition of claim 192, wherein the at least one hydrophilic polymer is a mixture of at least two hydrophilic polymers.

197. (Previously Presented) The composition of claim 192, wherein the carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

198. (Previously Presented) The composition of claim 192, wherein the carrier particles are present in an amount from 10 to 75% by weight; the micronized fenofibrate is present in an amount from 5 to 50% by weight; and the hydrophilic polymer is present in an amount from 20 to 60% by weight.

199. (Previously Presented) The composition of claim 198, wherein the carrier particles are present in an amount from 20 to 50% by weight; the micronized fenofibrate is present in an amount from 20 to 45% by weight; and the hydrophilic polymer is present in an amount from 25 to 45% by weight.

200. (Previously Presented) The composition of claim 192, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

surfactant.

201. (Previously Presented) The composition of claim 192, further comprising at least one surfactant.

202. (Previously Presented) The composition of claim 201, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture of two or more thereof.

203. (Previously Presented) The composition of claim 201, wherein the surfactant is sodium lauryl sulfate.

204. (Previously Presented) The composition of claim 201, wherein the surfactant is present in an amount from 0.1 to 3% by weight.

205. (Previously Presented) The composition of claim 192, wherein the composition further contains at least one pharmaceutical excipient.

206. (Previously Presented) The composition of claim 205, wherein the at least one pharmaceutical excipient is at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, or a mixture of two or more thereof.

207. (Previously Presented) The composition of claim 192, wherein the inert carrier particles are hydrosoluble.

208. (Previously Presented) The composition of claim 201, wherein the inert carrier particles are hydrosoluble.

209. (Previously Presented) A composition comprising granulates, wherein the granulates comprise carrier particles coated with an admixture comprising at least one hydrophilic polymer and micronized fenofibrate particles; wherein the carrier particles have a particle size between 50 and 500 microns; and wherein the weight ratio of micronized fenofibrate particles to hydrophilic polymer is between 1:10 and 4:1.

210. (Previously Presented) The composition of claim 209, wherein the carrier particles have a particle size between 100 and 400 microns.

211. (Previously Presented) The composition of claim 209, wherein the carrier particles comprise lactose.

212. (Previously Presented) The composition of claim 209, wherein the composition is in the form of a tablet.

213. (Previously Presented) The composition of claim 209, wherein the hydrophilic polymer is polyvinylpyrrolidone.

214. (Previously Presented) The composition of claim 209, wherein the composition further comprises at least one pharmaceutical excipient.

215. (Previously Presented) The composition of claim 214, wherein the at least one pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

216. (Previously Presented) The composition of claim 209, wherein the granulates further comprise at least one outer phase and/or layer.

217. (Previously Presented) The composition of claim 209, wherein the at least one outer phase and/or layer comprises at least one pharmaceutical excipient.

218. (Previously Presented) The composition of claim 217, wherein the at least one pharmaceutical excipient is selected from the group consisting of at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, and a mixture of two or more thereof.

219. (Previously Presented) The composition of claim 209, wherein two or more of the granulates are agglomerated together.

220. (Previously Presented) The composition of claim 209, wherein the micronized fenofibrate particles have a particle size of less than or equal to 20 μm.

221. (Previously Presented) The composition of claim 209, wherein the carrier particles are comprised of lactose, saccharose, hydrolyzed starch, or a mixture of two or more thereof.

222. (Previously Presented) The composition of claim 209, wherein the carrier particles are hydrosoluble.

223. (Previously Presented) The composition of claim 209, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture of two or more thereof.

224. (Previously Presented) The composition of claim 209, further comprising at least one surfactant.

225. (Previously Presented) The composition of claim 224, wherein the surfactant is sodium laurylsulfate.

226. (Previously Presented) The composition of claim 224, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture of two or more thereof.

227. (Previously Presented) The composition of claim 224, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

228. (Previously Presented) The composition of claim 209, wherein the carrier particles are present in an amount of 10 to 75% by weight, the micronized fenofibrate is present in an amount of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

229. (Previously Presented) The composition of claim 228, wherein the carrier particles are present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

230. (Previously Presented) The composition of claim 209, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

231. (Previously Presented) The composition of claim 209, wherein one or more of the carrier particles are isolated and/or agglomerated together.

232. (Previously Presented) The composition of claim 209, wherein the at least one hydrophilic polymer is a mixture of at least two hydrophilic polymers.

233. (Previously Presented) The composition of claim 209, wherein the carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

234. (Previously Presented) A method for preparing the composition of claim 209, comprising the steps of:

(a) preparing a micronized fenofibrate suspension in a solution comprising at least one hydrophilic polymer, and, optionally, at least one surfactant;

(b) spraying the micronized fenofibrate suspension from step (a) onto inert carrier particles having a particle size between 100 and 400 microns to form granules in a fluidized-bed granulator; and

(c) optionally coating the granules from step (b) with one or more phase(s) or layer(s).

235. (Previously Presented) The method of claim 234, further comprising compressing the granules of step (b) or step (c).

236. (Previously Presented) The composition of claim 192, wherein the micronized fenofibrate particles have a particle size of less than or equal to 20 μm.

237. (Previously Presented) The composition of claim 236, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

238. (Previously Presented) The composition of claim 220, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

239. (New) The composition of claim 192, wherein the composition is in the form of a tablet.